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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,346	01/20/2006	Jane Hirsh	CPX-015.01	1923

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
06/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,346	HIRSH ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/15/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 05/26/10 and a new IDS filed on 06/15/10. Abstarct and claims 1 and 12 have been amended, and no claims have been added or cancelled. Accordingly, claims **1 and 3-18** remain pending.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060140984) in view of Davis (5,143,717) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al '984 disclose an **alcohol-free cosmetic or pharmaceutical foam** carrier comprising water, a hydrophobic solvent, a foam adjuvant agent, a surface-active agent and a water gelling agent (see abstract). The said alcohol-free foamable carriers, when placed in an aerosol container and combined with a liquefied gas propellant, create an oil in water emulsion, which upon release from the aerosol container, provides a therapeutically beneficial foam product (see [0025]). The foam carrier includes active agents, both water soluble and oil soluble (see [0063]). The foam is easily spreadable, allowing treatment of large areas as the arms, back, legs and breast (see [0064]). Examples of suitable propellants include volatile hydrocarbons such as butane and fluorocarbon gases (see [0115]). Examples of suitable active agents include antibiotics, antifungals, anesthetics, anti-inflammatory agents, corticosteroids, etc (see [0226]). Anti-inflammatory agents include clobetasone, betamethasone, diclofenac, ketorolac, ibuprofen (see [0245] and [0252]-[0257]). Anti-fungals include fluconazole, ketoconazole, clotrimazole, etc (see [0234] to [0237]). Antibiotics include penicillins, macrolides, beta-lactams, etc ([0229]). Anesthetics include lidocaine, bupivacaine, dibucaine, etc (see [0264]). Example 8 discloses a foam formulation comprising antibacterials in an amount of about 2%. Example 9 discloses a foam formulation comprising 1-2% antifungals. Example 10 discloses foam formulations comprising 0.05 to 1% of corticosteroid anti-inflammatory agents. Example 18 discloses

a foam formulation comprising 4% lidocaine. Example 1 discloses a method of preparing the foam formulations.

Tamarkin et al '984 lacks disclosure on the oil phase being solid or semi-solid at room temperature. This deficiency has been remedied by Davis.

Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Sachetto.

Davis teaches burn foam and delivery system. The said foam is an antibiotic formulation useful in the treatment of burns and abrasions and adapted for topical application as a clinically water soluble foam (see abstract). The process steps in preparation of the said foam formulation include **heating and melting** the white petrolatum and other ingredients until all dints are melted and thoroughly to form the **oil phase** of the emulsion (see col. 4, lines 26-40). In a table on columns 5-6, multiple formulations have been exemplified with the concentration of each component. Examples VI-XV appear to contain an oil phase that is less than 3% (white petrolatum at 2.45%). The formulations also comprise a mixture of propane and isobutene as the propellant portion.

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such

as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al '984, Davis and Sachetto on forming foam compositions with a reasonable expectation of successfully preparing stable foam formulations for treating various disorders topically. Tamarkin et al teach an alcohol-free foam composition where the oil phase is liquid at room temperature and Davis teaches a foam formulation where the oil phase is solid at room temperature. Tamarkin discloses that the foam formulations comprise a propellant and Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art could have selected the solid phase of Davis over the liquid phase of Tamarkin et al with predictable results. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060233721) in view of Quigley, Jr. et al (6,075,056) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al '721 teach foamable composition for administration to the skin, body surface, body cavity or mucosal surface, e.g. the mucosa of the nose, mouth, eye, ear, respiratory system, etc. The foamable oil in water emulsion composition includes: an oil globule system, selected from the group consisting of oil bodies; and sub-micron oil globules, about 0.1% to about 5% by weight of an agent, selected from the group consisting of a surface-active agent, having an HLB value between 9 and 16 and a polymeric agent and a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the total composition, water and optional ingredients are added to complete the total mass of 100% (see abstract and [0012]). The said foamable composition further includes at least one therapeutic agent such as an anti-inflammatory agent, antifungal or antibacterial, anesthetics etc (see [0026]). A polar solvent such as polyols ([0064]). The foamable compositions may be substantially alcohol-free, i.e. **free of short chain alcohols**, having up to 5 carbon atoms in their carbon chain skeleton (see [0066]). The formulations may be in an oil-in-water emulsion ([0080]). Suitable propellants include volatile hydrocarbons and fluorocarbon gases ([0098]). Claim 1 is drawn to a foamable oil in water emulsion composition comprising an oil globule, a non-ionic surface active agent, water and a liquefied propellant.

Tamarkin et al '721 does not disclose an oil phase wherein the emulsion is a solid or semi-solid at room temperature. This deficiency has been remedied by Quigley et al. Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Sachetto.

Quigley, Jr. et al teach stable topical formulations comprising an antifungal agent and an anti-inflammatory steroid useful for treating fungal diseases and their related inflammation (see abstract). The topical formulations may be in the form of foam, cream, lotion, solution, etc (see col. 7, lines 31-34). To prepare the oil phase of the said topical formulations, it is said that the drugs are dissolved in the oil phase consisting of melted oil-soluble components of the formulation prior to addition of this phase to the aqueous phase (see col. 8, line 65 to col. 9, line 3). Other examples disclose similar process steps. Quigley et al also discloses that "white petrolatum is an emollient cream base and can be replaced by mineral oil" (see col. 8, lines 50-51). The cream formulations in Tables A and B show formulations comprising less than 10% oil phase (from 2 to 10% glycerin in Table A and from 1-20% white petrolatum in Table B).

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have

been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al '721, Quigley, Jr. et al and Sachetto on stable topical formulations comprising active agents such as antifungal agents and anti-inflammatory steroids useful for treating various diseases with a reasonable expectation of successfully preparing stable and effective topical foam preparations. Tamarkin et al teach foam formulations wherein the oil phase is a liquid at room temperature and the formulations are substantially free of lower alcohols. Quigley teaches topical formulations that can be in the form of foam and wherein the oil phase of the oil-in-water emulsion is soli or semi-solid at room temperature and is mixed with the aqueous phase after being melted. Tamarkin discloses that the foam formulations comprise a propellant and Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art would have been able to select the solid oil phase of Quigley and the substantially free of alcohols foam formulation of Tamarkin et al with expected results. That is, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally, the claims would have been obvious because a person of ordinary skill has

good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1, 12 and 13** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 48 and 49 of copending Application No. 11/552,457 (US 20070154402) in view of Tamarkin et al (US 20060140984).

The provisional obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not

patentably distinct from the reference claims because the examined claims would have been obvious over the reference claims. Here, instant claims are drawn to a topical foam aerosol formulation comprising an active agent dispersed in an oil-in-water emulsion and a propellant. The reference claims are also drawn to a topical foam aerosol formulation comprising an active agent dispersed in an oil-in-water emulsion and a propellant. The difference is that instant claims require the active agent be selected from active such as anti-inflammatory, anti-biotic, ant-fungal agents. The reference claims require the active agent be a keratolytic agent. the reference claims (claim 4) requires that other active agents such as anti-biotics and anti-inflammatories be added. Tamarkin et al however teaches alcohol free foam formulations that may comprise one or more active agents selected from a group consisting of anti-inflammatory agents, anti-biotics and keratolytics. Thus it would have been obvious to one of ordinary skill in the art to have substituted one active agent for the other as Tamarkin et al teaches that any one or more of the listed active agents can be successfully be delivered topically be the carrier foam formulation.

This is a provisional obviousness-type double patenting rejection.

Response to Remarks

Applicant's arguments filed 05/26/10 have been fully considered but they are not persuasive.

Applicant argues that “Sachetto describes aqueous foamable compositions comprising active agents, surfactants and foaming agents. The foaming agents

described are liquefied gases, such as propane, butane, isobutene, as well as HFA 134a and HFA 227 (page 4, and table 1). However, the only exemplification provided is for compositions comprising butane as the foaming agent; no compositions comprising HFAs are exemplified, and Sachetto provides no teaching as to why butane and HFAs would reasonably be considered interchangeable.". This is not found persuasive because: 1) A disclosure is not required to exemplify all embodiments. In other words, "disclosed examples and preferred embodiments do not constitute a teaching away from the broader disclosure or non-preferred embodiment." ***In re Susi,*** 440 F.2d 442, 169 USPQ 423 (CCPA 1971). 2) Sachetto, specifically teaches that suitable foaming agents are propenae, butane, isobutene, pentane and mixtures of these alkanes. Sachetto also discloses that "more recently developed environmentally friendly propellants such as 134a/p and HFA227 **are** suitable for use as foaming agents **in the present invention**" (see page 4, last paragraph). Thus clearly Sachetto teaches that either alkanes or HFAs would be suitable for the foaming formulations of Sachetto.

Applicant also argues that Sachetto describes delayed foaming formulations and that "teaches away from the using a hydrofluorocarbon propellant for an immediate foaming composition". This arguments is not persuasive and is not commensurate with the scope of claims. Sachetto does not teach away form using HFAs in delayed foaming formulations. As recited above, Sachetto specifically states that HFAs are suitable as foaming agents in the present invention. Furthermore , there is no distinction between delayed foaming formulations and others in the instant claims as they do not exclude delayed foaming compositions.

Applicant than refers to Exhibits D and E which were submitted on 12/22/09 and states that "HFA propellants were not 'drop in' replacement for CFCs in pMDIs" (see remarks, page 9). This is not persuasive because it is well know that CFCs are not safe or environmentally friendly. Thus one would be motivated to replace them. As HFAs are the most common replacement, one of ordinary skill in the art would be motivated to at least try them first. Thus meeting the motivation of "obvious to try". Furthermore, as shown Sachetto clearly teaches that HFAs are a suitable choice for foaming formulations.

Then Applicant argues that "Remarkably, HFA and CFC propellants differ significantly in their polarities and solubilities in water. In addition, they differ significantly in their ability to dissolve pharmaceutical active ingredients and common pharmaceutical surfactants. Exhibits D and E further explain the then-widespread belief that it was necessary, for example, to incorporate volatile lower alcohols as co-surfactants in order for HFA propellants to function as replacements for CFC propellants. For example, the abstract of Exhibit E explains that:

> *[c]onventional (CFC soluble) surfactants are effectively insoluble in the major CFC replacement candidates, HFA 134 and HFA 227ea, in the absence of co-solvents. While these ethane and propane derivatives have comparable boiling points and vapor pressures to dichlorodifluoromethane (CFC 12), their increased polarity demands that formulators use either alternative (soluble) surfactants, or co-solvents along with traditional surfactants, in order to stabilize pressurized suspension products.*

In other words, one of ordinary skill in the art would have understood that he or she would not have a reasonable expectation of success in maintaining the operability

and efficacy of a CFC- containing formulation upon substituting an HFA for the CFC. Moreover, because the rejected claims specifically require that the formulations "not contain volatile lower alcohols" nor contain "co-solvents or co-propellants" (i.e., the very things which are suggested in the art to make HFA formulations workable as replacements for CFCs), the Applicants respectfully assert that based on the state of the art, as summarized by Exhibits D and E, one of ordinary skill in the art would not have had a reasonable expectation of success in preparing the claimed formulations" (see page 9 of Remarks).

This is not found persuasive because there is no requirement for surfactants to be dissolved in propellants in the claims. In fact active agents can be dissolved or dispersed in an oil in water emulsion. Furthermore, the claims do not require a surfactant. Additionally it is noted that Tamarkin et al teaches foam formulations without the use of co-solvents or co-propellants. Tamarkin teaches use of propellants such as fluorocarbon gases, however it does not name HFAs as the suitable propellants. Sachetto was relied upon for its disclosure of various propellants including HFAs for foam formulations. Thus the combination of the references are proper and would lead one of ordinary skill in the art to the claimed invention.

Applicant makes no argument regarding the rejection of claims under obviousness-type double patenting. The said rejection is maintained.

Claims 1 and 3-18 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
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